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EXAMINER	
STUART, COLIN W	
ART UNIT	PAPER NUMBER
3771	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,643	CHALVIGNAC, PHILIPPE	
	Examiner	Art Unit	
	COLIN STUART	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-16 and 18-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-16 and 18-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 May 2010* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to the amendment filed 10/20/10. As directed by the amendment no claims have been amended, added, nor cancelled. As such, claims 1-4, 6-16, and 18-24 are pending in the instant application.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6-16, and 18-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: it appears that the apparatus of claim 1 is lacking an essential element to perform the function of detecting the new inspiratory or expiratory cycles of the patient, it appears that the calculation means is missing the program to determine inspiratory/expiratory cycles from the speed signal detected by the speed sensor (programs found in dependent claims 6 & 12 for example; it appears that the method claim 15 is missing essential elements for performing the claimed method steps of providing speed signals, computing pressure settings and determining inspiratory/expiratory cycles of the patient such as the speed sensor, control means and programs for determining cycles.

Also in regards to claim 1, it is unclear how the control means, which includes calculation means *detects* a new inspiratory or expiratory cycle of the patient. It appears from the disclosure that the speed signal is detecting the speed of the turbine and in turn sends this signal to the control/calculation means for *determining* existence of new inspiratory/expiratory cycles of the patient.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1, 3-4, 6-9, 11, 13, 15-16, 18-21, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen (2003/0015200) in view of Kullik et al. (6,895,962).

In regards to claim 1, Hansen shows a breathing assistance device which includes a turbine to generate a flow of pressurized respiratory gas (204 & 206; see para. 0026 and Fig. 2), a duct 214 adapted to carry the pressurized gas to a patient (see Fig. 2), and control means 250 for controlling gas pressure capable of computing a pressure setting for the turbine (see para. 0034), wherein the turbine is connected to a speed sensor 234 capable of acquiring a signal corresponding to a rotation speed of a rotating element of the turbine (see para. 0034 ln. 13-18; rotating element of turbine is impeller or fan see para. 0026 ln. 2-3), and the control means includes means of calculation connected to the speed sensor to compute the pressure setting using only said speed signal and send the pressure setting to the turbine (note that control means

250 is a processor which has calculation means to compute pressure settings; see also para. 0034 ln. 13-14 and para. 0041-0042 for computation of pressure setting using only speed sensors), the means of calculation being adapted to detect new inspiratory (see para. 0041) or expiratory cycles (see para. 0042) using only the speed signal (para. 0034 ln. 13-14), and consequently adapted a level of pressure setting. The Hansen device is silent as to the turbine having an inertia less than about 200 $g.cm^2$; however, Kullik teaches a breathing assistance device which includes a turbine having an inertia less than about 200 $g.cm^2$ (see Kullik col. 3 ln. 13-15). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the turbine of Hansen's device to have an inertia less than about 200 $g.cm^2$ as taught by Kullik in order to make "possible respiration with different respiration pressures" (see Kullik col. 1 ln. 20-21).

In regards to claim 3, the modified Hansen device includes speed sensor capable of acquiring a turbine speed signal directly connected to the rotation speed of the rotating element of the turbine (see para. 0034 ln. 13-18).

In regards to claim 4, the modified Hansen device includes means of calculation which computes the pressure setting according to variations in speed (see para. 0041-0042).

In regards to claims 6-7 and 11, the modified Hansen device further includes a program (see para. 0035) for detecting inspiratory cycle which includes a comparison between a speed value stored in a memory of the device (see para. 0035 ln. 12-14; pressure/flow profiles include speed values), the speed value being extrapolated using

recent values of measured speeds, and an actually measured instantaneous speed (see para. 0041-0042).

In regards to claim 8, the modified Hansen device includes a program (see para. 0035) for detecting inspiratory cycle (see para. 0041) using comparison between stored speed values at an end of the expiratory cycle and an actual measured instantaneous speed. Note that the device includes stored ventilation pressure/flow breathing profiles (para. 0035) and it is continuously monitoring speed signal of the turbine and uses the speed at the end of the expiratory cycle as this is the point where the patient's breathing cycle turns from expiratory to the inspiratory phase which is what the control means is determining (see para. 0041).

In regards to claims 9 and 21, the modified Hansen device includes several programs for detecting inspiratory cycles operating simultaneously, and is capable of computing pressure setting corresponding to a start of inspiratory cycle as soon as one of the programs has signaled a start of inspiration. Note that para. 0041 shows program for detecting inspiratory cycle and para. 0042 shows a program for detecting expiratory cycle and therefore if the program for detecting expiratory cycle does not detect the expiratory cycle the control means is capable of determining that the patient is in the inspiratory cycle. Furthermore, one of ordinary skill in the art at the time of the invention would have found it obvious to use various programs simultaneously for comparison to increase the accuracy of the inhalation/exhalation detecting process.

In regards to claim 13, the modified Hansen device includes means of calculation which includes a microprocessor connected to the speed sensor and to a turbine pressure setting input (see para. 0035 ln. 4 see Fig. 2).

In regards to claims 15-16, 18-20, and 23, the modified Hansen device lacks a detailed description of the claimed method steps. However, Hansen's system has the same structure as claimed. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made upon seeing Hansen's system, that the system would be able to perform the claimed method steps.

5. Claims 2 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen (2003/0015200) and Kullik et al. (6,895,962) as applied to claim 1 above, and further in view of Farrugia et al. (6,332,463).

In regards to claim 2, the modified Hansen device teaches all the limitations as discussed above, but is silent as to the speed sensor being a Hall effect sensor. However, one of ordinary skill in the art at the time of the invention would have found this to be a matter of obvious design choice as a Hall effect sensor is well-known in the art and further taught by Farrugia's breathing assistance control method (Abstract line 3).

In regards to claim 14, the modified Hansen device teaches all the limitations as discussed above including a circuit which connects the speed sensor, calculation means, and turbine for computing the speed setting input for the turbine (see para. 0034-0035 and 0041-0042), but is silent as to including a pressure-regulating loop

including a pressure sensor on the duct. However, Farrugia teaches a breathing assistance device and control method which includes a pressure sensor (42 Farrugia) which is connected to breathing tube, or duct, (40 Farrugia). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Hansen's device to include a pressure sensor as taught by Farrugia in order to provide a more direct, and accurate, measurement of the pressure of the breathing gas delivered to a patient.

6. Claims 10, 12, 22, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen (2003/0015200) and Kullik et al. (6,895,962) as applied to claims 6, 11, 18, or 23 above, and further in view of Rapoport et al. (5,803,066).

In regards to claims 10 and 22, the modified Hansen device teaches all the limitations as discussed above, but, as best understood, is silent as to providing that the device is configured to be disabled to compensate for the momentary pause between inspiratory and expiratory cycles. However, Rapoport teaches a breathing assistance device and control method which includes a pause state which allows the "machine is in transition from INSP to EXP, or from EXP to INSP" (Rapoport col. 7 ln. 56-57) for a determined duration following the start of the cycle. Therefore, one of ordinary skill in the art at the time the invention was made would have found it obvious to modify the modified Hansen's device and method to include a disabling means, or pause state, as taught by Rapoport in order to provide a more accurate control method for the breathing assistance device.

In regards to claims 12 and 24, the modified Hansen device uses a program for detecting expiratory cycle which uses comparison against a breathing profile stored in memory (see para. 0035) and is therefore capable of using a maximum speed stored and an actually measured instantaneous speed from the speed sensors. Furthermore, Rapoport teaches a breathing assistance device and control method in which the "system determines the maximum inspiratory flow value" (Rapoport col. 8 In. 39-40). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Hansen's device and method to also use memorized maximum turbine speed values for an inspiratory, as taught by Rapoport, in its comparison method in order to provide a more accurate control method as the modified method would be taking measurements from points through out the respiration cycles as opposed to focusing on the transitions from inspiratory to expiratory cycles.

Response to Arguments

7. Applicant's arguments with respect to claims 1-4, 6-16, and 18-24 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following documents are considered to be pertinent art: Jafari et al. (6,626,175), Champain et al. (5,443,061), and Servidio et al. (5,927,274) are all related to ventilation regulation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to COLIN STUART whose telephone number is (571)270-7490. The examiner can normally be reached on M-F 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). klf you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/COLIN STUART/
Examiner, Art Unit 3771

/Edward K. Look/
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